



## Better Health Care with Quality Medical Devices: FDA on the Cutting Edge of Device Technology

More than 20,000 firms worldwide produce over 80,000 brands and models of medical devices for the U.S. market, ranging from contact lenses and blood sugar monitors to implanted hip joints and heart valves. FDA's Center for Devices and Radiological Health (CDRH) makes sure that new medical devices are safe and effective before they are marketed. Many of these devices are the first of a kind, such as a robotic arm that can operate a variety of surgical tools with tremendous precision. Other high-tech devices are designed to prevent, diagnose or treat cancer, heart disease, impaired vision and hearing, and other health problems. The center also monitors devices throughout the product life cycle, including a nationwide postmarket surveillance system. And it assures that radiation-emitting products, such as microwave ovens, TV sets, cell phones, and laser products meet radiation safety standards.

The size of the CDRH workload is reflected in its performance statistics for last

year: 3,600 new products received marketing clearance, including 43 devices representing breakthrough technologies; 1,061 ongoing device trials were monitored; and 213 new clinical studies to test the safety and effectiveness of experimental devices in humans were approved.

Although its workload is

### Advances in Medical Device Technology

CDRH's approvals in 2000 included numerous state-of-the-art medical devices, such as:

- a system that enables a surgeon to perform intricate surgeries while sitting at a console with a computer and a video monitor and manipulating three robotic arms
- a system that measures oxygen saturation in a baby's blood as a sign of fetal health during labor and delivery
- a laser system that improves a physician's ability to distinguish small harmless growths from pre-cancerous growths in the colon
- the first mammography system that produces digital images on a solid state receptor instead of analog images on a radiographic film
- an implantable hearing aid for adults with moderate to severe hearing loss.

rapidly increasing, CDRH has streamlined its processes to reduce the average review time for novel and high-risk medical devices, which offer the greatest potential health benefits to patients. Between 1995 and 2000, approval times for these products declined from 26 months to 12 months.

In the near future, CDRH will be challenged to resolve complex issues connected with emerging technological and demographic developments, including:

- Diagnosis and treatment options related to the **human genome project**
- **Radiation safety** issues, including those associated with new medical imaging technologies
- **Breakthrough devices** using artificial intelligence, nanotechnology and robotics
- Special needs of our **aging population** for prosthetics, cardiac interventions, and home health care.

**For more information**, please call CDRH at 301-443-4690, or visit FDA's Web site at [www.fda.gov/cdrh](http://www.fda.gov/cdrh).